510(k) Summary

NCS Fish-Fit MD System

DEC 1 1 2012

K120356

1. **Submitted by:** NCS Lab Srl
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Preparation: November 27, 2012

2. **Device Name and Classification Information:**

Trade/Proprietary Name:

NCS Fish-Fit MD System, which consists of the following:

1) the Fish-Fit MD, a sterile, single use, implantable suture anchor; and,

2) the Compass MD, a series of reusable surgical instruments used to implant the Fish-Fit MD.

Common/Usual Name:

Anchor

Orthopedic Manual Surgical Instruments

Classification Information

NCS Fish-Fit MD System

Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener

Classification Regulation: 21 CFR 888.3040

Regulatory Class: II

Product Code: MBI – Fastener, Fixation, Nondegradable, Soft Tissue

3. Predicate Devices

The NCS Fish-Fit MD System is substantially equivalent to the following predicate devices:

- Smith and Nephew, TwinFix Ultra Ti Suture Anchor, cleared by FDA on April 19, 2010 in K100159; and
- ConMed Linvatex, Y-Knot All-Suture Anchor, cleared by FDA on August 8, 2011 in K111779.

4. Description of the Device

NCS Fish-Fit MD System is an implantable anchor made from Titanium grade 4. Sutures are not pre-assembled with bone anchor. The system includes an instrumentation package, Compass MD. The instrument package is intended to facilitate implantation of the anchor.

5. Intended Use and Indications for Use

The NCS Fish-Fit MD System is intended for use for the reattachment of soft tissue (tendons) to bone in the shoulder for rotator cuff repairs. The device has the following indications for use:

> *The NCS Fish-Fit MD System is intended for the attachment of soft tissue to bone during arthroscopic or open treatment of rotator cuff tendons lesions with the purpose of repairing the rotator cuff (supraspinatus, infraspinatus and subscapularis).*

6. Comparison to the Predicate Devices

The NCS Fish-Fit MD System is substantially equivalent to the legally marketed predicate devices. The NCS Fish-Fit MD System

and its predicate devices are all smooth or threaded metallic bone fixation fastener as defined in 21 CFR 888.3040.

The NCS Fish-Fit MD System has the same intended use as both predicate devices. All three devices are intended for use during arthroscopic or open surgeries to repair rotator cuff injuries. All three devices serve the same primary function: namely, to secure the tendons to bone during healing. All three devices are used by the same health care providers (orthopedic surgeons) in the same target patient population: adults who require repair of rotator cuff injuries. All devices are implanted into a cavity drilled into the bone.

All three devices share similar design features, including materials, similar sizes and dimensions, and insertion into a pre-drilled cavity into the bone. Each device utilizes a slightly different design to fix the anchor to the bone. Data have been provided to show that the NCS Fish-Fit MD System and Bone Anchor perform as well as the predicate device with respect to fixation strength and pull-out strength. These data have been provided in accordance with the FDA guidance document entitled "Guidance Document for Testing Bone Anchor Devices" dated April 20, 1996 to show that the NCS Fish-Fit MD System.

The provided non-clinical testing has been performed to verify adequate fixation strength and pull-out performances of the device, demonstrating substantially equivalence to the predicate devices.

7. Conclusion

Based upon the similarities in performances, materials and intended uses, NCS Fish Fit MD System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NCS Lab SRL
% Mr. Matteo Mantovani
Technical Director
Via Pola Esterna 4/12
Carpi, Italy 41012

Letter dated: December 11, 2012

Re: K120356
Trade/Device Name: NCS Fish-Fit MD System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 27, 2012
Received: November 29, 2012

Dear Mr. Mantovani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120356

Device Name: NCS Fish-Fit MD System

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey Hanley

For Division of Orthopaedic Devices